IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION (TOLEDO)

TINA BURRIS, Plaintiff, v. ETHICON, INC., et al., Defendants.	CASE NO. 3:20-cv-01450 JUDGE JAMES R. KNEPP II **MEMORANDUM IN SUPPORT OF DEFENDANTS' RULE 50(a) MOTION FOR JUDGMENT AS A MATTER OF LAW**

INTRODUCTION

Plaintiff has been fully heard on all of the evidence she has in support of her claims, yet she has not presented legally sufficient evidence from which a reasonable jury can conclude that a defect in Ethicon's Prolift warnings was the *cause* of her injuries. During Plaintiff's case, her implanting physician—Dr. Desrene Brown—testified that at the time she implanted Plaintiff's Prolift mesh in 2008, she was aware of a wide variety of risks, including but not limited to the risk of erosion, chronic pain, chronic pain with sexual intercourse (dyspareunia), foreign-body responses, vaginal scarring, urinary problems, recurrence or failure, contraction/shrinkage of tissue, and the need for additional potential surgeries. Dr. Brown testified she knew these not only due to her own professional experience and education, but also because Ethicon warned her and other implanting surgeons through professional education courses and materials. In short, Dr. Brown's testimony confirms what other Ethicon witnesses testified to—that the Prolift Instructions for Use ("IFU"), on which Plaintiff myopically focuses, are *not* the only way Ethicon warns doctors.

Further, even if this Court concludes that warnings causation presents a jury question, judgment as a matter of law is appropriate on Plaintiff's punitive damages claim. Not only has

Plaintiff not presented the jury with evidence rising to the level of malicious conduct, but also the statutory caps on noneconomic and punitive damages enacted by Ohio's General Assembly preclude an award of punitive damages. Because these caps apply to Plaintiff's claims, even when taking all of the evidence presented by Plaintiff at face value, Plaintiff may not recover punitive damages in this action as a matter of law.

LAW AND ARGUMENT

I. Plaintiff has not introduced legally sufficient evidence to prove proximate cause.

To prove a failure-to-warn claim under the Ohio Products Liability Act, Plaintiff must prove "an injury that is proximately caused by the breach." *Fulgenzi v. PLIVA, Inc.*, 140 F. Supp.3d 637, 647 (N.D. Ohio 2015) (quoting *Monroe v. Novartis Pharm. Corp.*, 29 F. Supp.3d 1115, 1125 (S.D. Ohio 2014)). Specifically, Plaintiff must provide evidence on *two* separate issues: (1) whether lack of adequate warnings contributed to the plaintiff's use of the product; and (2) whether use of the product constitutes a proximate cause of the plaintiff's injury. *See, e.g., Sheffer v. Novartis Pharms. Corp.*, No. 3:12CV0238, 2013 WL 5276558, at *11 (S.D. Ohio Sept. 18, 2013). In other words, Plaintiff must prove warnings causation *and* medical causation.

Plaintiff's warnings-causation evidence is legally insufficient. In the context of a prescription medical device, the relevant inquiry is whether a medical device manufacturer has adequately warned *the implanting surgeon*—not Plaintiff herself. Plaintiff must prove that an inadequate warning given to her implanting physician, Dr. Brown, was the *proximate cause* of Dr. Brown's decision to recommend the product, and she cannot make that showing if the evidence shows that Dr. Brown was already aware of the risks or complications alleged by the patient. *See, e.g., Fulgenzi v. PLIVA, Inc.*, 40 F. Supp.3d 637, 651 n. 12 (N.D. Ohio 2014) (relying on *Fullington v. Pfizer, Inc.*, 720 F.3d 739, 747 (8th Cir. 2013) for the proposition that "[a] manufacturer's

inadequate warning is not a proximate cause of a plaintiff's harm so long as the prescribing physician had independent knowledge of the risk that the inadequate warning should have communicated."); *Cutter v. Ethicon, Inc.*, No. 5:19-443-DCR, 2020 WL 109809, at *8 (E.D. Ky. Jan. 9, 2020) (plaintiff cannot show proximate cause on a failure-to-warn claim where implanter knew risks); *Sharp v. Ethicon, Inc.*, No. 2:20-CV-2028 WL 1434566, at *4 (W.D. Ark. Mar. 24, 2020) (failure to warn claim dismissed when physician knew of risks); *Nix v. Ethicon, Inc.*, No. 1:19-cv-04896-SCJ, 2020 WL 5525172, at *2 (N.D. Ga. Sept. 14, 2020) (same).

Dr. Brown's testimony that she was independently aware of the risks related to mesh surgery breaks the chain of causation. Specifically, Dr. Brown testified that she was aware of *all* of the following risks of mesh implantation *at the time* she implanted Prolift in Plaintiff:

- Acute and/or chronic pain with intercourse;
- Acute and/or chronic pain;
- Vaginal scarring;
- Infection;
- Urinary problems;
- Organ/nerve damage;
- Bleeding;
- Inflammation;
- Neuromuscular problems;
- Additional surgery;
- Recurrence or failure;
- Foreign body response;
- Contraction/shrinkage of tissues; and
- Erosion/exposure/extrusion.

Tr. Vol 5 at 890:22-894:4. That Dr. Brown was aware of *all* of those complications in August 2008 means Plaintiff cannot identify any defect in Ethicon's warnings that would have informed Dr. Brown of a risk of which she was not already aware.[1]

[1] Ethicon acknowledges that Dr. Brown testified that she would not have implanted Prolift in Plaintiff *if* she had been warned about certain risks presented to her by Plaintiff's counsel, but her testimony is not competent evidence to oppose judgment as a matter of law given Dr. Brown's

Plaintiff's likely response—that Ethicon should have provided a *stronger* warning, or more information about complication rates, in the IFU—merely distracts from the bigger picture. Plaintiff has maintained a laser-focus on Ethicon's IFU, but the jury has heard from multiple witnesses explaining that the IFU is not the only way Ethicon warns implanters. Plaintiff's only case-specific expert, Dr. Niall Galloway, conceded:

> Q. And you would agree with me that there are sources of information available to doctors about medical device procedures and products, other than the IFUs, right?
> A. I would agree.
> . . .
> Q. And not just training in medical school, residency, fellowship but also have **continuing education, professional education and training**, correct?
> A. Yes, and promotional events.
> Q. And when writing your report in this case, **you did not review what Ethicon professional education Dr. Brown had received on Prolift, did you?**
> **A. I did not**.

Tr. Vol. 4 at 749:25-750:21 (emphases added).

Dr. Galloway's testimony is consistent with numerous Ethicon witnesses' testimony, such as Charlotte Owens, Ethicon's Medical Director from 2003 to 2005, who when asked whether the IFU was the "primary" way in which Ethicon educated pelvic floor surgeons, corrected:

> A. I don't know if it's the first thing they would look to **because this would have been part of our entire professional education package; so this would be one of the things** they look to, yes.

Tr. Vol. 2 at 158:1-4 (emphasis added). Similar testimony was provided by Ethicon Medical Director Piet Hinoul, who testified about Ethicon professional education to pelvic floor surgeons, which he began providing around 2006. *See* Tr. Vol. 3 at 282:16-22; 339:21-22. And the nature of

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unequivocal testimony that she *was* aware of this same list of complications at the time she implanted Plaintiff's Prolift.

this professional education was described in greater detail by Dr. David Robinson, Ethicon Medical Director from 2005 to 2010:

> Q. All right. So doctor, with respect to a physician who may be choosing to use Prolift, did Ethicon provide doctors with additional training and educational materials unique to Prolift?
>
> . . .
>
> A. Well, **we provided not only instructions for use**, which are required, **but additional abundance of professional education**, including seminars including videos, including preceptorships, proctorships, the availability for those people to remain available, to a user of our product to ask questions, continuing seminars for our users of the products. So, in essence, **we tried to provide whatever was asked for in the way of training by the users or potential users**.

Tr. Vol. 4 at 634:22-635:12 (emphases added).

Dr. Brown's testimony underscores the problem with Plaintiff's emphasis on the IFU because Dr. Brown unequivocally testified that she relied on *numerous* sources of information, including professional education from Ethicon, *not* just the IFU. Tr. Vol. 5 at 859:12-861:5. And indeed, Dr. Brown testified about information (like slide decks) Ethicon presented to medical professionals during that educational training that addressed additional rates and types of complications beyond just the information contained in the IFU. *See* Tr. Vol 5 at 880:19-885:18. These sources provided implanters with additional information about mesh exposure rates (Tr. Vol. 5 at 883:1-6), dyspareunia (Tr. Vol 5 at 883:7-14), treatment options (Tr. Vol. 5 at 884:1-15), and the need for potential mesh removal (Tr. Vol. 5 at 885:14-18). Dr. Brown testified that she remembered seeing this slide deck. Tr. Vol. 5 at 917:20-25 ("[W]e all sat there and saw the slides. . . Safe to assume that I saw it."). While Dr. Brown could not recall whether she had seen some of the aspects of Ethicon's professional education presented to her during these previous courses, Plaintiff has provided *no* evidence on the record to suggest that the risks she alleges Ethicon warned of were not in fact included among its professional education materials.

While the focus of Ethicon's motion is on Plaintiff's insufficient proof of warnings causation, which requires dismissal of her case as a matter of law, Plaintiff has also failed to make a sufficient evidentiary showing as to a number of issues related to medical causation. For example, Plaintiff has attempted to make an issue of several alleged complications of Prolift—including distortion of the vaginal cavity affecting sexual function, increased risk of complications with concurrent hysterectomy, and degradation of mesh material—even though there is no case-specific evidence that Plaintiff herself experienced these specific complications, which makes proving medical causation impossible. For example, while Plaintiff has introduced evidence about alleged degradation in polypropylene mesh *generally*, she has not introduced *any* evidence to show degradation of her mesh, specifically. Just as significantly, Plaintiff has presented no competent evidence to establish that mesh degradation—*if* it occurs—has clinical consequences for patients.

Moreover, in some cases the evidence admitted at trial specifically negates the medical complications alleged by Plaintiff as factors in Plaintiff's case, such as Plaintiff's own concession and Dr. Brown's testimony that Plaintiff's hysterectomy was *not* concurrent with her Prolift implant. *See* Tr. Vol. 3 at 451:10-17; Tr. Vol. 5 at 874:19-875:2. Ethicon therefore requests that, if this Court declines to grant judgment as a matter of law on Plaintiff's warnings claim, this Court at least enter judgment as a matter of law as to medical issues not supported by the evidence introduced by Plaintiff and exclude any discussion of those conditions from closing argument.

II. Punitive damages are not recoverable as a matter of law.

Plaintiff's punitive damages case fails for two reasons: (1) because Plaintiff has not provided evidence sufficient to award punitive damage under Ohio law; *and* (2) because the combined operation of Ohio's statutory caps on noneconomic and punitive damages preclude punitive damages as a matter of law.

A. Plaintiff has not presented evidence of malicious conduct or aggravated fraud sufficient to meet the "clear and convincing" standard required by Ohio law.

Punitive damages may only be awarded under Ohio law if Plaintiff proves "by clear and convincing evidence" that the defendants' "actions or omissions . . . demonstrate malice or aggravated or egregious fraud." R.C. 2315.21(C)(1) & (D)(4). Plaintiff has not presented evidence sufficient to clear the hurdle. At most, the evidence presented by Plaintiff supports the proposition that Ethicon was aware of potentially stronger warnings that it could have, but did not use in the IFU, but presented through other educational material provided to Prolift implanters. That is not evidence of willful, wanton, or malicious conduct reaching the high standard for punitive damages under Ohio law.

B. Plaintiff presented evidence of economic damages sufficient to establish a maximum possible damages amount of $683,246.

Ohio's statutory caps on noneconomic and punitive damages can be readily applied so long as it is possible to calculate a plaintiff's maximum award of alleged *economic* damages. Here, doing so is possible because the *only* evidence presented to the jury related to an amount of economic damages is the testimony of Robert P. Tremp, Jr., who testified to the jury about the Life Care Plan and Vocational Report he prepared. Mr. Tremp testified as to two categories of economic damages: amounts needed to carry out his Life Care Plan for Plaintiff (a total of $262,626) and lost wages (a total of $246,900 based on the projected Social Security retirement age of 67). Tr. Vol 5 at 958:3-20. Combined, Mr. Tremp testified that these amounts equal $508,526. Tr. Vol. 5 at 961:7-11. In addition, Mr. Tremp noted that Plaintiff stopped working seven years ago—accounting for at most $174,720 in retrospectively lost wages. *See* Tr. Vol. 5 at 957:24-958:5. In total, her maximum potential economic damages supportable by the evidence are $683,246.

C. Ohio R.C. 2315.18(b)(2) limits Plaintiff's maximum recovery for noneconomic damages to $350,000.

Plaintiff's alleged noneconomic damages are likewise calculable. The Ohio Revised Code caps the amount of noneconomic damages available at $350,000 per plaintiff:

> (2) Except as otherwise provided in division (B)(3) of this section, the amount of compensatory damages that represents damages for noneconomic loss that is recoverable in a tort action under this section to recover damages for injury or loss to person or property **shall not exceed** the greater of two hundred fifty thousand dollars or **an amount that is equal to three times the economic loss**, as determined by the trier of fact, of the plaintiff in that tort action **to a maximum of three hundred fifty thousand dollars for each plaintiff** in that tort action or a maximum of five hundred thousand dollars for each occurrence that is the basis of that tort action.

R.C. 2315.18(b)(2) (emphases added). There are only two exceptions, which are listed in R.C. 2315.18(b)(3). The cap on noneconomic damages does not apply "if the noneconomic losses of the plaintiff are for either of the following":

> (a) Permanent and substantial physical deformity, loss of use of a limb, or loss of a bodily organ system;
> (b) Permanent physical functional injury that permanently prevents the injured person from being able to independently care for self and perform life-sustaining activities.

R.C. 2315.18(b)(3). Plaintiff does not argue that the second exception applies.

1. Plaintiff has not made a legally sufficient evidentiary showing that she experienced a "permanent and substantial physical deformity" such that R.C. 2315.18(b)(3) does not apply.

Numerous Ohio and federal courts have applied Ohio's cap on noneconomic damages as a matter of law. *See, e.g.*, *Sheffer*, 2014 WL 10293816 at *2 (observing that Ohio R.C. 2315.18(E)(2) "specifically permits this issue to be decided on summary judgment."); R.C. 2315.18(E)(2) ("Prior to the trial in the tort action described in division (D) of this section, any party may seek summary judgment with respect to the nature of the alleged injury or loss to person or property, seeking a

determination of the damages as described in division (B)(2) of this section."). Thus, for a plaintiff to "lift the cap" on noneconomic damages, the plaintiff must first "cross[] an evidentiary threshold" by identifying sufficient evidence of a "permanent and substantial physical deformity" such that the issue is one "for the[] jury, not the court to decide." *Sheffer*, 2014 WL 10293816 at *2. *See also Fairrow v. OhioHealth Corp.*, 2020-Ohio-5595, ¶ 68 (Ohio Ct. App.) ("The trial court must determine whether there is enough evidence to meet the basic evidentiary threshold. Once that threshold is met, it is for the trier of fact, not the court, to determine whether the damages constitute permanent and substantial deformity."); *Swink v. Reinhart Foodservice, LLC*, No. 3:20 CV 1997 (N.D. Ohio 2022) (quoting *Fairrow*, 2020-Ohio-5595 at ¶ 68).

Plaintiff has not presented evidence sufficient to cross the threshold. When Ohio's General Assembly enacted the statute, it did not define the phrase "permanent and substantial physical deformity." But subsequent Ohio and federal court decisions have clarified the standard. The Ohio Supreme Court has explained that a "permanent and substantial physical deformity" refers to "catastrophic" injuries. *Arbino v. Johnson & Johnson*, 116 Ohio St.3d 468, 2007-Ohio-6948, 880 N.E.2d 420, ¶ 47. The standard is an objective one. *Weldon v. Presley*, No. 1:10 CV 1077, 2011 WL 3749469 at *7 (N.D. Ohio Aug. 9, 2011) ("Ohio courts have interpreted 'permanent and substantial deformity' objectively.").

In *Arbino*, the Ohio Supreme Court summarized the legislative rationale for the noneconomic damages cap. Drawing from the General Assembly's Findings of Fact and Intent, the Supreme Court explained:

> The General Assembly's general justification for the tort reforms in S.B. 80 was that the state has an "interest in making certain that Ohio has a fair, predictable system of civil justice that preserves the rights of those who have been harmed by negligent behavior, while curbing the number of frivolous lawsuits, which increases the cost of doing business, threatens Ohio jobs, drives up costs to consumers, and may stifle

> innovation." S.B. 80, Section 3(A)(3), 150 Ohio Laws, Part V, 8024. . . . **In regard to noneconomic injuries, it noted that awards for such injuries are inherently subjective and susceptible to improper inflation**. *Id.* at Section 3(A)(6)(a), (c), and (d). It also found that "[i]nflated damage awards create an improper resolution of civil justice claims." *Id.* at (e).

Arbino, 116 Ohio St.3d at 482, 2007-Ohio-6948 at ¶ 68 (emphasis added).

The statute does not define "permanent and substantial physical deformity," but courts have used the other injuries that *are* identified in the same statutory provision—particularly, "loss of use of a limb" and "loss of a bodily organ system"—as a guidepost:

> "Loss of use of a limb" appears fairly straight forward. The Merriam Webster Dictionary defines a limb as a "leg or arm" of a human being. No longer being able to use an arm or leg certainly seems like a significant injury that the Ohio General Assembly had in mind when creating the exceptions to the damages cap. The United States District Court for the Southern District of Ohio defined "loss of bodily organ system" in a recent decision. There the court held that the complete loss of sight in one eye fell short of a loss of bodily organ system. In order for the plaintiff to have suffered a loss of bodily organ system, she needed to have lost complete use of her "ocular system," which she had not, as she was able to see partially out of her other eye.

Weldon v. Presley, No. 1:10 CV 1007, 2011 WL 3749469, at *6 (N.D. Ohio Aug. 9, 2011). Given "the extreme qualifications required for the other injuries listed," courts have held that for a deformity to be "permanent and substantial," it "must be severe and objective." *Id.*; *see also Adams v. Durrani*, 183 N.E.3d 560, 574, 2022-Ohio-60, ¶ 66 (1st Dist.) (same); *Sheffer*, 2014 WL 10293816 at *2 (same).

Neither Plaintiff nor her spouse have testified that the "deformity" she attributes to a removal of a portion of her Prolift mesh during a surgery performed by Dr. Goldman at the Cleveland Clinic in October 2021 is "substantial" or alleged that it affects Ms. Burris's physical abilities in any way. *See* Tr. Vol. 2 at 207:5-12; Tr. Vol. 3 at 472:7-474:14. Plaintiff herself described it as follows:

A. It's kind of like an indent. Just like a big chunk missing out of your leg, but like an indent I would say.
Q. Is it something that's physically -- that you can physically see?
A. Well, my husband can, but nobody else would.

Tr. Vol. 3 at 474:10-14.[2]

The scar that Plaintiff's counsel describes as a "deformity" is not the kind of catastrophic injury described by the Supreme Court of Ohio in *Arbino*. Plaintiff testified that her husband is the only person who even sees it, and that it does not bother him. Tr. Vol. 3 at 474:19-21. He testified the same. Tr. Vol. 2 at 211:16-20. No witness and no document in evidence has ever described it as "substantial," let alone presented objective evidence that it is. And there is no evidence or testimony that connects this "deformity" to any other physical consequences for Plaintiff.

Courts generally hold that "substantial physical deformities" are those which have a long-term impact on the normal function of the body. Even then it is not always enough. For example, in *Sheffer v. Novartis Pharmaceuticals Corp.*, the court addressed whether osteonecrosis leading to a broken jaw, which Plaintiff attributed to a defective prescription drug, was a "substantial" physical deformity exempting the plaintiff's claims from the cap on noneconomic damages. The court concluded that even though the plaintiff testified "her jaw 'will never be perfect,' and she still suffers some jaw pain, . . . her injury is not the type of catastrophic 'permanent and substantial physical deformity' contemplated by § 2315.18(3)(a)." 2014 WL 10293816 at *2 (internal citation omitted). This was the case even though the plaintiff's jaw injury caused her long-term consequences in the form of being unable to eat "raw vegetables and other foods that are 'hard or crunchy or extremely chewy.'" *Id.* In other instances, courts that have permitted this issue to go to a jury require a showing of major anatomical changes that accompany the "deformity." *See Ross*

[2] An image of the scar Plaintiff referenced in her testimony is in evidence as PX 514. The parties have stipulated to the authenticity of this photo. Tr. Vol. 3 at 482:23-484:8.

v. Home Depot USA, Inc., No. 2:12-cv-743, 2014 WL 4748434, at *6-7 (S.D. Ohio Sept. 23, 2014) (concluding that the alleged existence of a substantial deformity was a jury question where it was described as 'multiple 'misshapened,' 'unnatural,' and 'distorted' conditions in both her left knee and shoulder' that "required a significant amount of hardware to be implanted into her body'"); *Ohle v. DJO Inc.*, No. 1:09-cv-02794, at *2 (finding that there was a jury question regarding the existence of a "substantial physical deformity" where the plaintiff lost "nearly all" of her shoulder cartilage, had her shoulder replaced with a metal prosthesis, and had a "large raised keloid scar from her collar bone to her armpit and two smaller keloid scars on the front of her shoulder."); *Setters v. Durrani*, 2020-Ohio-6859 at ¶ 38 (concluding that the existence of a substantial physical deformity was a jury question where "all of the treating doctors and experts agreed that Setters's spinal anatomy changes as a result"); *Adams v. Durrani*, 2022-Ohio-60 at ¶¶ 68-69 (finding that "the issue was properly before the jury primarily because of the 'restructuring' of Adams's spine and the 'deformity of stance and gait.'"); *White v. Bannerman*, 2010-Ohio-4846, ¶ 87 (applying exception to the noneconomic damages cap where a plaintiff child testified regarding substantial scarring on hands and face resulting in disability in the use of her hands and need for pain medicine because of the scarring).

D. In light of Plaintiff's maximum potential recovery for compensatory damages, Ohio law precludes an award of punitive damages.

1. Plaintiff's maximum possible award for punitive damages under Ohio R.C. 2315.21(D)(1)(a) is $2,066,492.

Section 2315.21(D)(1) of the Ohio Revised Code prohibits an award of punitive damages "in excess of two times the amount of the compensatory damages awarded to the plaintiff" from a defendant. Here, as explained above, Plaintiff's maximum possible compensatory damages award is $1,033,246—$683,246 in economic damages plus $350,000 in noneconomic damages. As such,

taking all of Plaintiff's allegations as true, the maximum amount of punitive damages available to Plaintiff under Ohio law—on her best day and if the jury finds in her favor on all of her alleged injuries—is $2,066,492.

2. But R.C. 2315.21(D)(5)(a) provides that the Court "shall not award" punitive damages because Ethicon where—as here—Ethicon has paid *more than eight times* that amount in punitive damages in previous Prolift cases.

Ohio law prohibits multiple punitive damages awards:

> In any tort action, except as provided in division (D)(5)(b) or (6) of this section, punitive or exemplary damages **shall not be awarded** against a defendant if that defendant files with the court a certified judgment, judgment entries, or other evidence showing that punitive or exemplary damages have already been awarded and have been collected, in any state or federal court, against that defendant based on the same act or course of conduct that is alleged to have caused the injury or loss to person or property for which the plaintiff seeks compensatory damages and that the aggregate of those previous punitive or exemplary damage awards exceeds the maximum amount of punitive or exemplary damages that may be awarded under division (D)(2) of this section against that defendant in the tort action.

R.C. 2315.21(D)(5)(a) (emphasis added). But Ethicon has paid punitive damages in multiple other cases involving Prolift. At least two of these cases have resulted in judgments awarding punitive damages to plaintiffs who have sued Ethicon in failure-to-warn litigation.

First, Ethicon was sued in the Superior Court of New Jersey in a case captioned *Gross v. Gynecare, et al.*, No. ATL-L-6966-10. In *Gross*, the jury found Ethicon responsible for a failure to warn the plaintiff regarding risks associated with the Prolift system. *See Gross* Jury Interrogatories (Liability), attached as Exhibit A. The jury then awarded $7,760,000 in punitive damages. *Gross* Jury Verdict Form, attached as Exhibit B; *Gross* Order of Judgment, attached as Exhibit C. Ethicon paid these punitive damages on January 23, 2017. *Gross* Warrant of Satisfaction of Judgment, attached as Exhibit D.

Second, Ethicon was sued in the Northern District of Indiana in a case captioned *Kaiser v. Johnson & Johnson, et al.*, No. 2:17cv114. The Plaintiff in *Kaiser* raised a claim for punitive damages (Count XVII) based on, among other things, Ethicon's alleged failure to warn (Count III) of risks associated with the Prolift device, which was the only product implanted in the Plaintiff. *Kaiser* Am. Compl. at ¶¶ 8-9, 13, attached as Exhibit E. The jury awarded a verdict encompassing a finding of negligent failure to warn and assessing $25 million in punitive damages. *Kaiser* Final Verdict Form, attached as Exhibit F. The *Kaiser* court, however, concluded that the $25 million punitive damages award was "excessive and unreasonable" and remitted the award to $10 million. *Kaiser* Opinion and Order at 2, attached as Exhibit G. Ethicon accordingly paid the $10 million punitive damages judgment in April 2020. *Kaiser* Satisfaction of Judgment, attached as Exhibit H.

Like Plaintiff, the plaintiffs in *Gross* and *Kaiser* alleged that Ethicon willfully, maliciously, and consciously disregarded patient safety in formulating the Prolift warnings. Plaintiff alleges that very same course of conduct. Because this is the same course of conduct under which the plaintiffs in *Gross* and *Kaiser* were awarded and collected punitive damages from Ethicon, and because they did so in an amount that far exceeds the maximum that Ethicon could be liable for in this case, Plaintiff cannot seek to recover those same damages.

3. No exception to Ohio R.C. 2315.21(D)(5)(a) applies.

Finally, Plaintiff cannot avoid the statutory mandate that this Court "shall not award" punitive damages in excess of the $17.76 million paid in previous cases by arguing that either of the exceptions to the statute in R.C. 2315.21(D)(5)(b) applies. These exceptions apply in only two sets of scenarios:

- Where the plaintiff offers "new and substantial evidence of previously undiscovered, additional behavior of a type" demonstrating malice or aggravated or egregious fraud, R.C. 2315.21(D)(5)(b)(i); or

- Where the Court "determines by clear and convincing evidence that the total amount of prior punitive or exemplary damages awards was *totally insufficient* to punish that defendant's behavior" and "to deter that defendant and others from similar behavior in the future," R.C. 2315.21(D)(5)(b)(ii).

There is no evidence to support either exception. The company documents and witnesses introduced into evidence in this case are the same documents that have been introduced in numerous Prolift cases tried both before the MDL Court and in other courts upon remand over the past decade. The first exception therefore cannot apply. Nor is there any evidence to suggest that the $17.76 million paid in the two previous Prolift cases, *Gross* and *Kaiser*, was "totally insufficient." To be clear, any such conclusion would run counter to the decision made by the court that *awarded* the damages in the *Kaiser* Prolift case, which remitted the original $25 million award to $10 million after concluding that it was "excessive and unreasonable." *Kaiser v. Johnson & Johnson*, 334 F. Supp. 3d 923, 947-48 (N.D. Ind. 2018) ("Here, while the jury heard evidence and the parties stipulated to defendants' net worth being $70 billion, the award of $25 million represents *over 166 times the amount of relevant profits earned by defendants* which from the perspective of the defendant is clearly excessive."). The *Kaiser* court therefore remitted the damages award to $10 million. *Id.* at 948. The Seventh Circuit affirmed that award as "reasonable." *See Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1020 (7th Cir. 2020). In addition, there is no similar behavior to deter in regards to the Prolift, as the product is no longer marketed. *See* Doc. 122, DE Motion *in Limine* No. 4 to Exclude Evidence Concerning the Decommercialization of Prolift and TVT-Secur.

CONCLUSION

For the reasons described above, which will be elaborated on by Ethicon's counsel during its argument on the record regarding its Rule 50(a) motion, Ethicon requests that this Court grant

judgment as a matter of law in its favor and dismiss both Plaintiff's failure-to-warn claim and her request for punitive damages.

Respectfully submitted,

/s/ Erica M. James
Tariq M. Naeem (0072808)
Michael J. Ruttinger (0083850)
Erica M. James (0086799)
TUCKER ELLIS LLP
950 Main Avenue—Suite 1100
Cleveland, OH 44113-7213
Telephone: 216.592.5000
Facsimile: 216.592.5009
Email: tariq.naeem@tuckerellis.com
michael.ruttinger@tuckerellis.com
erica.james@tuckerellis.com

Sherry Knutson (*pro hac vice*)
TUCKER ELLIS LLP
233 South Wacker Drive, Suite 6950
Chicago, Illinois 6060-9997
Telephone: 312.624.6322
Facsimile: 312.624.6309
Email: sherry.knutson@tuckerellis.com

Margaret H. Loveman (*pro hac vice*)
BUTLER SNOW LLP
1819 Fifth Avenue North, Suite 1000
Birmingham, AL 35203
Telephone: 205.297.2241
Facsimile: 205.297.2201
Email: margaret.loveman@butlersnow.com

Attorneys for Defendants
Ethicon, Inc. and Johnson & Johnson

CERTIFICATE OF SERVICE

I hereby certify that on July 17, 2022, a copy of the foregoing was filed electronically. Service of this filing will be made by operation of the Court's electronic filing system.

/s/ Erica M. James
Erica M. James (0086799)
One of the Attorneys for Defendants
Ethicon, Inc. and Johnson & Johnson